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Telephone:(0312)2183000Fax:(0312)2183460 Web:https://www.titck.gov.tr/ TurkishMinistryofHealth TurkishMedicinesandMedicalDevicesAgency GUIDELINEONAPPLICATIONSFORGMPINSPECTIONOF FOREIGNMANUFACTURINGSITES İDD-KLVZ-21 InitialVersionEffectiveDate 06.03.2015 1 st RevisionEffectiveDate 15.02.2018 2 nd RevisionEffectiveDate 02.07.2018 3 rd RevisionEffectiveDate 20.09.2022 4 th RevisionEffectiveDate 15.11.2022 5 th RevisionEffectiveDate 27.12.2022 6 th RevisionEffectiveDate 07.07.2023 7 th RevisionEffectiveDate 18.09.2023 8 th RevisionEffectiveDate 05.10.2023 9 th RevisionEffectiveDate 07.06.2024 10 th RevisionEffectiveDate 22.09.2025

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 1.Purpose

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ThisGuidelinesetsforththenormsandproceduresforreviewingapplicationsfor GoodManufacturingPracticeinspectionofmanufacturingsitesofhumanmedicinalproducts manufacturedabroadandproposedforimportationintoTürkiye,andforconducting inspections. 2.Scope ThisGuidelineappliestoapplicationsforGoodManufacturingPracticeinspectionand theinspectionprocessofhumanmedicinalproductsandadvancedtherapymedicinalproducts manufacturedabroadandproposedforimportationintoTürkiye.Humanmedicinalproducts, notyetgrantedmarketingauthorizationinTürkiyeand/orauthorizedbutunavailableonthe Turkishmarketforanyreason,whichareimportedintoTürkiyeonanindividualbasisunder theGuidelineonIndividualImportationandUseofHumanMedicinalProducts,where appropriate,alsofallwithinthescopeofthisGuideline. 3.LegalBasis 3.1RegulationonManufacturingSitesofHumanMedicinalProducts,publishedfor effectinOfficialGazette#30217of21.10.2017. 3.2RegulationonMarketingAuthorizationofHumanMedicinalProducts,published foreffectinOfficialGazette#31686of11.12.2021. 4.DefinitionsandAbbreviations Bulkproduct:Aproductthathasundergoneallstepsofthemanufacturingprocess, uptoandexcludingfinalpackaging. CEPCertificate:EuropeanPharmacopoeiaConformityCertificate. WHO:WorldHealthOrganization. Activesubstance:Anysubstanceormixtureofsubstancesintendedtobeusedinthe manufactureofamedicinalproductandthat,whenusedinitsproduction,becomesanactive substanceofthatproductintendedtoexertapharmacological,immunologicalormetabolic actionwithaviewtorestoring,correctingormodifyingphysiologicalfunctionsortomakea medicaldiagnosis. GMP:GoodManufacturingPractice. Agency:TurkishMedicinesandMedicalDevicesAgency. ÖDEK:PriorityAssessmentBoard. PIC/s:PharmaceuticalInspectionCo-operationScheme. Primarypackaging:Theprocessbywhichahumanmedicinalproductintendedfor theenduserisplacedinsidetheproductcontactcontainer/package. Referenceregulatoryauthority:Acredibleauthoritywhopreviously approved/authorizedthehumanmedicinalproductinquestion,andwhohadbeenproposedby themarketingauthorizationapplicantforuseasaguidelineforthemarketingauthorization process,includingWorldHealthOrganization(WHO),acompetentauthoritywhoisa foundingmember(U.S.FoodandDrugAdministration(USFDA),EuropeanMedicines Agency(EMA)andnationalcompetentauthoritiesofEUmemberstates,MinistryofHealth andWelfare,PharmaceuticalsandMedicalDevicesAgencyofJapan(PMDA))orpermanent member(NationalMedicinesAgencyofSwitzerland(Swissmedic),NationalMedicines AgencyofCanada(HealthCanada))competentauthoritiesoftheInternationalCouncilfor

Harmonization(ICH),TherapeuticGoodsAdministrationofAustralia(TGA)andHealthcare ProductsRegulatoryAgencyoftheUnitedKingdom(MHRA)). Secondarypackaging:Theprocessbywhichtheimmediatepackagingincontact withthehumanmedicinalproductisplacedinsideanoutercarton/package,including replacementofcarton,printing,applicationofbarcode/2D-barcode,applicationoftax label/label,insertionorreplacementofpackageleaflet/productinformation,orsimilar operations. Semi-finishedproduct:Partially-processedmaterialwhichneedstobefurther processedtobulkproduct. DistantInspection:Aninspectionmodelwheretheinspecteesubmitsdocuments relevanttotheinspectionviaaninstitutionalinbox,aninstitutionalelectronicdocument system,orareliablefilesharingprogram,orbypersonallydeliveringthedocumentsin hardcopyforreviewatthetaskcenter,andwhichisbasedoninspectionofthefacilityusing distantaccesstechnologies,whereappropriate. HybridInspection:Aninspectionmodelwhere–aftertheinspectorconcludesthatan

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on-siteinspectioniswarranted–documentsrelevanttotheinspectionareprovidedbeforeor aftertheinspectionforreviewatthetaskcentertominimizethetimespentonsite,followed byanon-siteinspectionofthefacility. 5.Introduction TheRegulationonManufacturingSitesofHumanMedicinalProductsdefineshuman medicinalproductmanufacturingsiteasafacility,oragroupoffacilities,whichareinvolved inweighing,dispensation,primarypackaging,secondarypackaging,andprocessingto finishedproductofstartingmaterialsusedinthemanufacturingprocessofmedicinalproducts and/oractivesubstances,includingassociatedcontrolsandbatchreleaseoperations. AccordingtotheRegulationonMarketingAuthorizationofHumanMedicinal Products,applicantsmustsubmitacertificateissuedbyourAgencytothemanufacturingsite forallmanufacturingstepsoftheproductgrantedorpendingmarketingauthorization,orfor specificstepsofthemanufacturingprocessforwhichacertificateisnotissuedbyourAgency, acertificaterecognizedbyourAgency,issuedbyacompetenthealthauthority,showingthat themanufacturingoperationsareconductedinlinewithinternationally-recognizedguidelines forgoodmanufacturingpractice,orwhereacertificateinhardcopyisnotavailable,anotice orcertificaterecognizedbyourAgency,showingthatthemanufacturingoperationsare conductedinlinewithinternationally-recognizedguidelinesforgoodmanufacturingpractice, oraGMPcertificate,issuedbythecompetentauthorityofacountrywhichsignedamutual recognitionagreementwithTürkiye,showingthatthemanufacturingoperationsare conductedinlinewithinternationally-recognizedguidelinesforgoodmanufacturingpractice. ForapplicationsforGoodManufacturingPracticeinspectionofmanufacturingsitesof humanmedicinalproductsmanufacturedabroadandproposedforimportationintoTürkiye, andfortheinspectionprocess,thereports,GMPcertificatesandothersimilarinformationor documentsrelatedtoinspectionsconductedbycompetentauthoritiesofcountrieswith comparablestandards,orbyregionalorinternationalagencies,mayberegardedunderArticle 13,Paragraph9oftheRegulationonManufacturingSitesofHumanMedicinalProducts,and theGuidelineonRelianceProcedureforEvaluationofGoodManufacturingPractice, currentlyinforce.

Inthispremise,thefollowingpointsshouldbeconsideredregardingapplications, inspectionsandpost-inspectionproceduresforon-site/paper-based/risk-basedGMP inspectionsofproductsmanufacturedabroadandproposedforimportationintoTürkiye.

6.PrinciplesforGMPInspectionScope

6.1.GMPinspectionsofactivesubstancemanufacturing(see6.3,6.4,6.5,6.6,and6.7), semi-finishedproductmanufacturing(see6.8and6.9),bulkmanufacturing,primary packaging,secondarypackaging,laboratorieswherequalitycontroltestsareperformed,batch release(see6.11),andsolventmanufacturing(see6.10)activitiesofproductsmanufactured abroadandimportedtoourcountryareconductedaspertheprovisionsofthisguideline.

6.2.Whereallmanufacturingstagesarecarriedoutatthesamemanufacturingsite,theGMP inspectionconductedbyourAgencywillcoverallstages. Incaseofsplitmanufacturing;

6.3.Manufacturingfacilitiesofactivesubstancesofconventionalproductswillnotbe includedintheinspectionscope,withoutprejudicetoourAgency'srighttoinspect.

6.4.Whereactivesubstancesofallergenicproductsareproducedatalocationdifferentfrom themanufacturingsitetobeinspected,withoutprejudicetoourAgency'srighttoinspect, suchfacilitieswillnotbeincludedintheinspectionscope.

6.5.Regardinghomeopathicstockmanufacturingsitesforhomeopathicmedicinalproducts, anapplicationmustalsobesubmittedwithintheguidelinesforGMPinspectionofthe manufacturingsitesofhomeopathicstocksfallingwithinthescopeofnosodeandsarcode.

6.6.Whetheactivesubstancesofbiotechnological/biosimilarproducts,biologicalproducts withbiologicalactivesubstances,andadvancedtherapymedicinalproductsaremanufactured atalocationdifferentfromthemanufacturingsitetobeinspected,anapplicationmustalsobe

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submittedforGMPinspectionofthemanufacturingsiteinquestion.
6.7.Whereestablishment,maintenance,preservation,andstorageofaMasterCellBank and/orWorkingCellBankarecarriedoutintheactivesubstancemanufacturingfacilitiesof biological,biotechnological/biosimilarproducts,andadvancedtherapymedicinalproducts, theseareasandprocessesareexaminedwithinthescopeoftheinspection.Iftheseactivities arecarriedoutatdifferentfacilities,ourAgencydoesnotrequireinspectionofthefacilities whereearlymanufacturingstagesarecarriedout,inaccordancewithAnnex2oftheGMP guideline.Withoutprejudicetotherighttoinspect,duringtheinspectionsoftheactive substancemanufacturingstagesofbiological,biotechnological/biosimilarproductsand advancedtherapymedicinalproducts,documents,certificatesandrecordsrelatedtothe processesinquestionshallberequestedandexamined,withnoseparateinspectioncarriedout andnoseparateGMPcertificateissuedforthementionedstages.

6.8.Regardingsemi-finishedproductmanufacturingfacilitiesforconventionalproducts:
-Ifthefacilitiesinquestionarelocatedincountriesotherthan Australia,theUnited Kingdom,orthefounding(USA,EUmemberstates,Japan)orpermanent(Canadaand Switzerland)memberstatesoftheInternationalCouncilforHarmonization(ICH)and donotholdacurrentGMPCertificateissuedbytheaforementionedauthorities,or;
-Iftheproductssubjecttotheapplicationdonotholda CEPcertificate, thenanapplicationmustalsobesubmittedforaGMPinspectionofthemanufacturing sitesinquestion,aspertheguidelines.
6.9.Ifthesemi-finishedproductmanufacturingstagesofbiological,biotechnological/ biosimilarproducts,andadvancedtherapymedicinalproductsarecarriedoutindifferent facilities,anapplicationmustalsobesubmittedforaGMPinspectionofthemanufacturing siteinquestion.
6.10.Ifsolventsforproductscontainingsolventsareproducedatalocationdifferentfromthe manufacturingsitetobeinspected,anapplicationmustalsobesubmittedforaGMP inspectionofthemanufacturingsiteinquestion.
6.11.Ifthemanufacturingstagesofsecondarypackagingand/orqualitycontroltestingforthe batchreleaseoffinishedproductsand/orfinalcontainersterilizationprocessesand/orfinished productbatchrelease,arelocatedatdifferentlocations,theselocationswillnotbeincludedin theinspectionscope,withoutprejudicetotherighttoinspect,ifdeemednecessary.
6.12.Forapplicationsregardingchangesand/oradditionstomanufacturingsites,ifproduct manufacturingoccursatmorethanonemanufacturingsiteandthesemanufacturingstep(s) havenotbeenpreviouslyinspectedbyourAgency,applicationsmustbesubmittedin accordancewiththeguidelinesforthefacilitywherethestep(s)inquestionareperformed.
6.13.Informationanddocumentsavailableatthemanufacturingsiteduringtheinspection mustalsobeavailableinEnglish.
6.14.Itisessentialthatthemanufacturingoftheproductforwhich aGMPinspectionis requestedbewitnessedduringtheinspection.Iftheproductforwhich aGMPinspectionis requestedisnotlicensedanywhereintheworldandisnotcurrentlybeingproduced,thepilot manufacturingoftheproductorthemanufacturingofanotherproductproducedonthesame lineandequipmentastheinspectedproductmustbewitnessedduringtheGMPinspection (suchthatallmanufacturingstepsincludingweighing,bulkmanufacture,primaryand/or secondarypackagingetc.canbeobserved).
6.15.Ifthefacilitytobeinspectedislargeand/ortheproductsrequestedforinspectionhavea largediversityand/orthenumberofproductsishigh,inspectionsmaybeconductedin multiplesessions.
6.16.Anyexplanatoryoradditionalinformationmayberequested,asdeemednecessary, duringtheapplicationorevaluationstagesoftheinspections.
6.17.Theapplicantcompanyandtheinspectedpartyareobligatedtotakethenecessary

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measurestoensuretheproperexecutionofinspectionactivities.Thisincludes;
-Ensuringcommunicationregardingtheinspectionplanning,
-Complyingwiththepromisedinspectionprogram,
-Communicatingtheinspectionagendatothemanufacturingfacility,

-Ensuringthenecessarytransfersfortheinspection,
-Completelypreparingandsubmittingdocumentsnotifiedbytheinspectorsorthe relevantunitaspartoftheinspection,
-Providingthedocumentsrequestedbytheinspectorsbeforeandaftertheinspection,
-Notifyingtheinspectedpartyoftheinspectionresults,andsubmittingtheresponses andsupportingdocumentspreparedbytheinspectedpartytoourAgency.

7.PrinciplesforGMPInspectionApplications

7.1.AccordingtotheRegulationonMarketingAuthorizationofHumanMedicinalProducts (specifically,Article7andArticlethereof),applicationsforon-site/paper-based/risk-based GMPinspectionmustbesubmittedbytheimporteroftheproductsestablishedinTürkiye, andthereforethedocumentsspecifiedinArticle8,Pointsa,b,candçoftheRegulationmust bealsosubmitted,inadditiontotherequisiteinformationanddocumentsspecifiedinthe relevantarticlesofthisGuideline.

7.2.Thecoverletterandtheapplicationformforanapplicationforon-site,paper-basedor risk-basedGMPinspectionmustbefreefromanyomissionsandcompletedseparatelyfor eachproduct,eachmanufacturingsiteandeachpharmaceuticalform,andattachedwitha copyofthecurrentmarketingauthorizationcertificateforapprovedproducts,andacopyof theGMPprioritydecisionbyÖDEK;alldocumentsmustbearasignature.Forproducts pendingmarketingauthorizationwhicharepreposedfortransfer[ofapplicationownership],a copyofthetransferagreementmustbeincludedinallapplicationssubmittedunderthis Guideline.

7.3.Applicationsmustconformtotherequirementsofthisguideline,andallassociatedfees mustbepaidinfull.Anyfailuretocomplywiththeforegoingrequirementwillresultin dismissalofapplication.

7.4.Thisguidelineanditsannexesapplytoallergenicproducts.Documenttypesfor allergenicproductsmustbeselectedforeachproduct.

7.5.Aseparateproduct/certificatefeemustbepaidforeachdifferentdosageandvolumeof eachproductcoveredbythelicense.

7.6.Wheredocumentsaretobesubmittedtoouragencydirectlybyaninspecteeabroad,the importershouldfirstmakeanapplicationelectronicallytohaveane-trackingnumber assignedbyourAgency'sproceduralsoftware;theinspecteeabroadshouldspecifythee-trackingnumber,theimporter'snameandtheproductnameontheircoverletter,andprovide thedocumentsonaCD,memorystickorexternaldrive(notinprintedform).Otherwise,it willnotbepossibletoprocessdocumentswhichcannotbeattributedtoaspecificapplication, andinthatcase,theresponsibilitywillliewiththeimporter.

7.7.Whereaproductismanufacturedatmultiplemanufacturingsites,theapplicationforon-site/paper-based/risk-basedGMPinspectionmustbesubmittedseparatelyforeachsuchsite, withtherequisiteinformationanddocumentsspecifiedintheannexeshereto;thecoverletter shouldspecifythemanufacturingoperationsperformedatthemanufacturingsiteconcerned foreachproduct(e.g.bulkproductionoperationsforproductA,primarypackagingoperations forproductB),andanapplicationdossiermustcoveronlyasinglemanufacturingsite.

7.8.Anyattachmentstoapplicationssubmittedtoouragencymustbegivenadesignation usingthenamingconventioninparentheses;theinformationanddocumentssubmittedmust becomplete,andsubmittedinthesameorderasprovidedontheapplicationform.

7.9.AlldocumentssubmittedtoourAgencymustbecurrent,preparedbythemanufacturing

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facilitysubjecttotheapplication,andsignedbythequalityassurancemanager, manufacturingmanager,orresponsiblemanageroftheaforementionedfacility.
7.10.Ifthetechnicalinformationanddocumentsfortheproductorthemanufacturingsiteare inanon-Englishlanguage,theirTurkishorEnglishtranslationshouldbeprovidedalongwith theoriginaldocument.Documentspreparedbyadifferentfacility/takenfromamarketing authorizationfile,documentsforwhichtheissuerfacilityisunclearand/ordocumentsthatare outdatedwillnotbeaccepted.
7.11.Toavoidredundancyintheapplicationdossier,cross-referencestoinformation previouslypresentedshouldbeusedwherepracticable.
7.12.Applicationsforchangesrelatedtoalterations/additionstorooms/lines/equipment withinthesamebuildingforproductsmanufacturedatmanufacturingsitesinspectedbyour agencyandpossessingavalidGMPcertificateissuedinaccordancewiththeseinspections mustbesubmittedbyselectingthedocumenttype“ForeignGoodManufacturingPractices (GMP)Notifications.”Wheresuchanapplicationisfoundtobeineligiblebyour Agency Inspectors,aninspectionapplicationmustbesubmittedinlinewiththeapplicableguideline.
7.13.a)Forproductssubjecttoapplicationsmade/tobemadetoourAgency,ifthereisany changeintheinformationaboutthemanufacturingfacility(facilitynameandaddress,etc.) withoutchangingitsphysicallocationandmanufacturingactivities:Fortheaccuracyofthe informationonwhichthecertificateisbased,thecurrentGMPcertificate,Manufacturing Site PermitCertificate,Annex3.ManufacturingSiteApplicationForm,andothernecessary supportingdocumentsmustbesubmitted.
b)Forproductswithmarketingauthorizationsubjecttoapplicationsmade/tobemade toourAgency,wherethereisanychangeintheinformationbelongingtotheimporter company:AletterofapprovalissuedbytheDirectorateofDrugLicensingoracopyofthe currentlicensereflectingthechange;forproductsthathavenotyetbeenlicensed,atransfer agreementandTradeRegistryGazettedocumentsmustbesubmitted.
c)Forproductswithmarketingauthorizationsubjecttoapplicationsmade/tobemade toourAgency,incaseofanychangeintheproductname:Anapprovalletterissuedbythe DirectorateofDrugLicensingoracopyofthecurrentlicensereflectingthechangemustbe submitted;forproductsthathavenotyetbeenlicensed,thecurrentAnnex1.Product ApplicationFormdocumentsmustbesubmitted.
7.14.Forproductsthathavebeeninspectedandforwhicha GMPcertificatehasbeen issued/willbeissued,asummarytableshowingtheadministrativeandtechnicalclassification ofchangesthatmustbereportedtoouragencyandtheprocedurestobefollowedforthese changesisprovidedinAppendix11.Whereaproposedchangeinproductormanufacturing sitedocumentsisclassifiedinthelow-riskcategory,itwillberegardedasachangenot warrantinginspectionandtheGMPcertificatewillberevisedtoalignwiththerequest.Where aproposedchangeisclassifiedinthemoderate-riskcategory,theGMPcertificatemaybe revisedasrequestedatourAgencyInspectors’discretion,orthecompanymaybeadvisedto applyforinspection.Whereaproposedchangeisclassifiedinthehigh-riskcategory,the applicantwillhavetoapplyforinspectioninlinewiththeapplicableguideline.

7.15.Whereanadditionalornewapplicationismadeforthepurposeofaddingaproduct(s) manufacturedatproductionsitesscheduledforon-siteinspectionwithinthescopeofthis guidelinetotheinspection,theapplicationmustbesubmittedinfullatleast15businessdays priortotheinspectiondateusingthedocumenttype“ForeignGoodManufacturingPractices (GMP)On-SiteInspectionApplication(Eachapplicationmustcoveroneproductionsite)”. Pre-inspectionpreparationandinspectionplanningarecarriedoutforproductscoveredbythe inspection.Asthesechangesaffectthescopeoftheinspectionandthenumberofinspection days,attentiontothesemattersisimportant.

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7.16.Followinganapplicationmadeunderthisguideline,requeststoexcludeproducts manufacturedatproductionsitesscheduledforon-siteinspectionmustbemadeusingthe “ForeignGoodManufacturingPractices(GMP)Notifications”documenttypeatleast15 businessdayspriortotheinspectiondate.Pre-inspectionpreparationandinspectionplanning arecarriedoutforproductswithinthescopeoftheinspection.Sincethesechangesaffectthe scopeoftheinspectionandthenumberofinspectiondays,attentiontothesemattersis important.
7.17.Where,afteraGMPcertificatewasissuedbyourAgencyandwithinthevalidititermof suchcertificate,ourAgencydeemsitnecessarytoconductaninspectionatthemanufacturing siteoftheproductscoveredbythecertificateduetoproduct-relatedreasons(e.g.product complaints,qualitydefects,OOSorsimilarfindings),theinspectee(s)mustpaytheon-site inspectionfees.Iftheinspectionfindsthemanufacturingoperationsoftheproductsconcerned tobeconformanttoGMPrequirements,anewGMPcertificatemaybeissuedwiththedateof thisinspection,iftheapplicantsorequestsandpaystheproduct/certificationfees.
7.18.ForGMPinspectionofhumanmedicinalproducts,whicharenotauthorizedinTürkiye orauthorizedbutunavailableonthemarketplaceforanyreason,andwhicharetobeimported undertheGuidelineonIndividualImportationandUseofHumanMedicinalProducts:inthe eventofarequesttoaddaproducttotheListofHumanMedicinalProductsApprovedfor IndividualImportation,theCommitteeforEvaluatingRequestsforIndividualImportationof HumanMedicinalProductsmay,accordingtoArticle9oftheaforesaidguideline,decidefor GMPinspectiononanindividualproductbasisfortheproductsconcerned,excluding productsmanufacturedatmanufacturingsiteslocatedincountrieslistedinArticle5, Paragraph3ofthisGuideline.Applicationsforsuchinspectionswillbegovernedbythis guideline,andmaybeconductedon-siteoronpaperbasis.Thediscretionlieswithrelevant committeesofourAgencytodetermineprioritizationofproductstobeinspectedforGMP compliance.
7.19.ForproductsprioritizedbyrelevantcommitteesofourAgencyinthecircumstances describedaboveinArticle7.18andscheduledtoundergoGMPinspection:

-AnapplicationunderArticleAofthisguidelinemustbemadeformanufacturing sitesrequiringon-siteinspectionandwhichhadnotbeenpreviouslyinspectedbyourAgency;
-AnapplicationunderArticleBofthisguidelinemustbemadeformanufacturing sitesthathadbeenpreviouslyinspectedbyourAgency.Inbothcases,therequisitedocuments forthecategoriesmustbesubmittedwithoutanyomissions.

8.PrinciplesforGMPPost-InspectionProcess
8.1.Thevalidityperiodofanon-siteinspectionmaybeupto9or12yearsfromthedateof inspection,inaccordancewithArticle8.3ofthisguideline.
8.2.UndertheprovisionsofArticleA(on-siteinspection),GMPcertificatesarevalidfora periodof3yearsfromtheinspectiondateofthemanufacturingsiteconcerned.GMP certificatesissuedafterarisk-basedinspectionarevalidforaperiodof3yearsfromexpiryof theprecedingcertificate.UndertheprovisionsofArticleB(paper-basedinspection),the validityperiodofGMPcertificatesissuedafterapaper-basedinspectionisthesameasthatof aGMPcertificateissuedforaproductinspectedon-site,coveredbytheapplication.
8.3.AnapplicationismadeunderArticleC(risk-basedinspection)toextendthevalidity periodofacertificateissuedasaresultofaninspectionconductedbasedonanapplication madeunderArticlesA(on-siteinspection)andB(paper-basedinspection)ofthisguideline (excludingpointd(solventproduction)).Themaximumvalidityperiodofaninspectionis -12yearsifthefacilitiesinquestionarelocatedinaPIC/smembercountry.For facilitieslocatedinthesecountries,threerisk-basedinspectionapplicationsmaybe submitted.(*Thisarticleappliestoapplicationsbasedonon-siteinspections conductedin2016andsubsequentyears.) 3years 3years 3years 3years Aninspectioncanbe validforamaximum of12years. Thereisarighttorenew oncefromtheinspection date.

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Whenthecertificateexpires, thereisnorighttorenewit since12yearshavepassed sincetheinspectiondate. On-SiteInspection Theinspectiondate istakenasbasisin determining certificatevalidity duration. 1.Risk-Based Inspection Mustbedone within9monthsat theearliestfromthe certificatevalidity expirydate. 2.Risk-Based Inspection Mustbedone within9monthsat theearliestfromthe certificatevalidity expirydate. 3.Risk-Based Inspection Mustbedone within9monthsat theearliestfromthe certificatevalidity expirydate. Paper-based Inspection 1.Risk-Based Inspection 2.Risk-Based Inspection 3.Risk-Based Inspection Paper-based Inspection 1.Risk-Based Inspection 2.Risk-Based Inspection Paper-based Inspection Risk-Based Inspection Paper-based Inspection

-ForfacilitiesnotlocatedinPIC/smembercountries,risk-basedinspectionapplications canbemadeforupto9years,andforfacilitieslocatedinthesecountries,risk-based inspectionapplicationscanbemadeuptotwice.

8.4.IfacurrentandvalidinspectionconductedbyourAgencyattherelevantfacilityexists forthepurposeofextendingthevalidityperiodofGMPcertificatesforproductswhoserisk-basedinspectionrighthasexpired,anapplicationmustbemadeunderArticleBofthe Guideline(paper-basedinspection);however,iftheconditionsofArticleBarenotmet,an on-siteinspectionapplicationmustbemade.

8.5.FollowinganapplicationmadeunderArticleB,pointd(solventproduction)ofthe Guideline,anewapplicationmaybemadewithcurrentdocumentsunderthesame article/pointfortherenewalofGMPcertificatesissued.

8.6.ProductswithGMPcertificatesissuedfollowinganapplicationmadeunderArticlesB andCoftheGuidelineshallbeincludedinthescopeofthefirston-siteinspectiontobe carriedoutatthefacilityinquestion.

8.7.Ifoneormorecriticaldeficienciesoranumberofmajordeficienciesthatwillbe evaluatedascriticaldeficienciesareidentifiedasaresultofon-siteinspectionsconductedin accordancewithArticleAofthisguideline,titled“CircumstancesandGeneralPrinciplesfor ConductingOn-SiteGMPInspectionsatForeignManufacturingSites,”thecertificate applicationwillberejected.Norepeaton-siteinspectionapplicationwillbeacceptedfora periodof6monthsstartingfromthedateofnotificationoftheinspectionresulttothe company.Attheendofthisperiod,theon-siteinspectionapplicationshallbeaccompaniedby thedocumentsspecifiedinArticleA,aswellassupportingdocumentsprovingthatthe deficienciesidentifiedduringtheinspectionhavebeenaddressedandthecurrentpriority assessmentdecisionfortheproductobtainedfromtherelevantcommitteeofourAgency.The inspectionfeesmustbepaidagainaftertheinspectioniscarriedout. 3years 3years 3years On-SiteInspection Theinspectiondateis takenasbasisin determiningcertificate validityduration. 1.Risk-Based Inspection Mustbedonewithin9 monthsattheearliest fromthecertificate validityexpirydate. 2.Risk-Based Inspection Mustbedonewithin9 monthsattheearliest fromthecertificate validityexpirydate. Paper-based Inspection 1.Risk-Based Inspection 2.Risk-Based Inspection Paper-based Inspection Paper-based Inspection Risk-Based Inspection Aninspectioncanbe validforamaximumof 9years. Thereisarighttorenew oncefromtheinspection date. Whenthecertificateexpires, thereisnorighttorenewit since9yearshavepassed sincetheinspectiondate.

8.8.Whereoneormorecriticaldeficienciesareidentifiedduringanon-siteinspection, resultingfromevaluationofanapplicationsubmittedunderArticleC,titled“Circumstances forConductingRisk-BasedInspection,”ofthisGuideline,thecertificatesoftheproduct(s) concernedwillberevokedandtheirimportationceased.Afterthecriticaldeficiencies,and anyotherdeficienciesraisedbyourAgency,havebeenresolved,anapplicationforon-site

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inspectionmaybesubmittedunderArticleAhereof;theapplicationshouldbeattachedwith anopinionletterfromtherelevantunitofourAgencyonwhetherunavailabilityofthe product(s)onthemarketplacewillcausehardshiptopatients,alongwiththedocumentslisted inArticleA,documentationofcorrectiveandpreventiveactionstakentoresolvethe deficiencies,andotherdocumentaryevidence.
8.9.Inmanufacturingsiteswhereoneormorecriticaldeficienciesareidentifiedduringon-siteinspections,actionsregardingotherproductsmanufacturedatthesiteandcertifiedbyour AgencyshallbetakeninaccordancewiththedecisionoftheInstitution.
8.10.AsaresultoftheevaluationconductedbyourAgency,forproductsthataredecidedto beinspectedon-siteorthathaveusedtheirrighttotwoorthreerisk-basedinspectionsinline withtheGuidelinebutfailtomeettheconditionsofArticleBoftheGuideline;regarding requestsfortheextensionofthevalidityperiodoftheirexistingGMPcertificates,provided thatanup-to-dateandvalidGMPcertificateissuedbyPIC/smemberauthoritiesforthe facilityissubmitted,applicationsmadeunderthedocumenttype“ForeignGood ManufacturingPractices(GMP)Notifications”shallbeevaluated,andthevalidityperiodof theexistingGMPcertificatesmaybeextended,onaone-timebasisonly,forupto12months fromthedateofexpiry.
8.11.Forrequeststoaddactivitiesforwhichaninspectionisnotmandatoryandwhichwere notinspectedduringtheon-siteinspectionandarenotincludedintheissuedcertificate,tothe certificateafterwards;thedecisionshallbemadebasedontheevaluationoftheapplication submittedunderthedocumenttype“ForeignGoodManufacturingPractices(GMP) Notifications”togetherwithsupportingdocumentssuchasalocalauthorityreportcovering therelevantactivities,areportissuedbyPIC/sauthorities,themanufacturingsitelicense,and anup-to-dateGMPcertificateofthefacility.
8.12.ForapplicationsforaccrualofGoodManufacturingPractices(GMP)certificates, regardingtheproductnamestobeincludedinthecertificate;acopyofthevalidmarketing authorizationshallbeincludedintheapplicationannexforauthorizedproducts,andfor unauthorizedproducts,thecurrentAnnex1:ProductApplicationFormshallbeincluded.
9.PrinciplesforHandlingCrisesandEmergencies
Considerationmaybegivenonthefollowingbasisincaseswhereconductinganon-siteGMPinspectionofamanufacturingsitelocatedabroadisprecludedduetonationalor internationalrestrictionsintroduced,inthepremiseofmeasurestakenbyourAgencyto mitigatedisruptionofmanufactureandsupplyofhumanmedicinalproductsresultingfrom restrictionsimposedduetoextraordinarycircumstancesposingarisktopublichealth, includingcrises,emergencies,outbreaksorpandemics,andtoensurepreservationofsupply ofandaccesstohumanmedicinalproductswhichpatientsneedfortreatment.

Theobligationsofimportersundercurrentlegislationstand,forproductsinrespectto whichtheyarethemarketingauthorizationholderorforwhichtheysubmittedamarketing authorizationapplication. WithoutprejudicetoourAgency’srighttoinspectthemanufacturingsites concernedatitssolediscretion,thefollowingprovisionswillapplyuntiltheprecautionsor restrictionshavebeenlifted: Withrespectto:
1.manufacturingsiteswhichhadnotbeenpreviouslyinspectedon-sitebyourAgency,
2.manufacturingsiteswhichhadbeenpreviouslyinspectedon-sitebyourAgency,but inrespecttowhichadecisiontoconducton-siteinspectionhasbeentakenafterreviewunder theguideline,and 3.manufacturingsiteswhichhadbeenpreviouslyinspectedon-sitebyourAgency,but whichhasundergonechanges/additionsthatwarranton-siteinspection, whichreceivedadesignation(ofhighpriorityorpriority)bythePriorityAssessment Boardmayqualifyforpaper-basedinspection–onanexceptionalbasis–providedthatithad undergoneinspectioninthepast3yearsbyacompetentauthoritypartytoPIC/sandthe

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

criteriaofArticleBoftheGuidelinehavenotbeenmet;
inthatcase,thefollowingdocumentsmustbesubmitted:
-Ifthemanufacturingsiteoperatesinacountrywhichishometoacompetent authoritypartytoPIC/s,thelastinspectionreportcoveringthemanufacturingline/areaused fortheproducts,issuedbythelocalcompetentauthorityoracompetentauthoritypartyto PIC/s;
-Ifthemanufacturingsiteoperatesinacountrywhichisnothometoacompetent authoritypartytoPIC/s,thelastinspectionreportcoveringthemanufacturingline/areaused fortheproduct,issuedbyacompetentauthoritypartytoPIC/s;
-Inadditiontotheup-to-dateandvalidInspectionReport,thefollowingdocuments listedinthisGuidelineshouldbesubmitted: a)Annex1.ApplicationFormfortheProduct
b)Annex2.ApplicationFormfortheActiveSubstance
c)Annex3.ApplicationFormfortheManufacturingSite
ç)Annex4.ADocumentationofTechnicalParticularsoftheManufacturingSite, RequiredforGMPInspectionofForeignManufacturingSites
d)Annex6.BTechnicalParticularsoftheProduct
e)Declaration/explanationregardinginabilitytomeetthecriteriaofArticleBofthe GuidelineonApplicationsforGMPInspectionofForeignManufacturingSites;and
f)GMPprioritydecisionsissuedbyÖDEK.

Dependingonwhetherthemanufacturingfacilityhaspreviouslybeeninspectedbyour Agency,theapplicationmustbesubmittedundertheappropriatedocumenttype.Applications willbeevaluatedbyourAgency'sInspectors,andifdeemednecessaryduringtheevaluation stage,additionaldocumentsmayberequestedfromtheimportingcompanies.Basedonthe outcomeoftheevaluation,adecisionwillbemadeastowhetheraGMPcertificatewillbe issued.
4.IncaseswheretheunitsorcommitteesorboardsoftheMinistryorourAgencyreport thatadisruptioninsupplyofthehumanmedicinalproductconcernedmaycausepublichealth problemsand/oravalidhighprioritydesignationdecisionhasbeengrantedfortheproduct concernedwithaviewtopreservingsustainabilityofhealthcareservices,adistantand/or hybridinspectionmaybeconducteduponanapplicationsubmittedunderthisguideline. Nevertheless,anapplicationforon-siteinspectionmustbesubmittedwithinnotmorethan1 yearafterthedistantand/orhybridinspectiondate,unlessprecludedbywar,naturaldisasters orotheremergencies.Thedocumentsthatmustbesubmittedforreviewinclude:
a)Annex1.ApplicationFormfortheProduct b)Annex2.ApplicationFormfortheActiveSubstance
c)Annex3.ApplicationFormfortheManufacturingSite
ç)Annex4.ADocumentationofTechnicalParticularsoftheManufacturingSite, RequiredforGMPInspectionofForeignManufacturingSites
d)Annex6DocumentsRequiredforPaper-BasedInspectionApplications
e)Thelastinspectionreportissuedbythelocalorothercompetentauthority,covering themanufacturingline/areaoftheproduct(s)coveredbytheinspection.
10.ProvisionsforGMPInspectionsUndertheExpeditedMarketingAuthorization ProcedureBasedonCollaborationwithWHO
ForhumanmedicinalproductswhichareincludedintheWHO prequalification/emergencyuselistorwhichweregrantedmarketingauthorization/approval byotherreferenceregulatoryauthoritiesundertheExpeditedMarketingAuthorization ProcedureBasedonCollaborationwithWHO,accordingtotheGuidelineontheReliance ProcedureforMarketingAuthorizationofHumanMedicinalProducts,whetherthefacility subjecttotheapplicationhasbeeninspectedbyourAgencywillfirstbeconsidered. Wherethefacilitysubjecttotheapplicationhaspreviouslybeeninspectedbyour Agencyandthevalidityofthatinspectionisstillineffect,theapplicationshallbeevaluated withinthescopeofArticleBoftheGuideline:CircumstancesandGeneralPrinciplesfor

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

ConductingPaper-BasedInspections.Wherethefacilitysubjecttotheapplicationhasnot previouslybeeninspectedbyourAgency,orwherethevalidityoftheinspectionisnolonger ineffect,apaper-basedevaluationmaybecarriedoutbasedonGMPinspectionreportsthat willbemadeaccessibletoourAgencybytheWHO,withinthescopeoftheReliance GuidelineforGoodManufacturingPractices(GMP)Assessments,withoutprejudicetoour Agency'srighttoinspecttherelevantfacilities.

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 15of34 Thefollowingdocumentsmustbesubmittedfortheseapplications: 1.Asignedandproperlyfilledoutcopyoftheformsprovidedin Annex3tothe GuidelineontheRelianceProcedureforMarketingAuthorizationofHumanMedicinal Productscurrentlyinforce; 2.FormsinAnnex1,Annex2andAnnex3tothisGuidelinefilledout,andthe documentslistedinAnnex4.AandAnnex6.Bwithoutanyomissions. Dependingonwhetherthemanufacturingsitehadbeenpreviouslyinspectedbyour Agency,theapplicationmustbesubmittedunderthedocumenttype:"ForeignGood ManufacturingPractices(GMP)Paper-basedInspectionAssessmentApplicationperProduct forMarketingAuthorization(excludingcertification)(ifaninspectionhaspreviouslybeen carriedoutatthefacilityonbehalfoftherelevantcompany)(co-marketingproductsshall alsobeevaluatedwithinthisscope)",or"ForeignManufacturingSitesGoodManufacturing Practice(GMP)Paper-BasedInspectionAssessmentApplicationforEachProductProviding BasisforMarketingAuthorization(excludingcertification)(ifaninspectionhadnotbeen previouslyconductedatthemanufacturingsiteforthisapplicant)",asappropriate.Agency Inspectorswillreviewtheapplications,andtheimportermayberequiredtosubmitadditional documentsifconsiderednecessaryduringreview.Theoutcomeofreviewwilldeterminethe decisiononwhetherornottoissueaGMPcertificate.

11.TypesofGMPInspectionofForeignManufacturingSites

A.CircumstancesandPrinciplesforOn-SiteGMPInspectionofForeignManufacturing Sites

Anapplicationforon-siteinspectionmaybesubmittedfor:

1.Manufacturingsitesnotpreviouslyinspectedon-sitebyourAgency,

2.Manufacturingsitespreviouslyinspectedon-sitebyourAgency,butrequiringon-siteinspectionbasedonreviewaccordingtotheguideline,

3.Manufacturingsitespreviouslyinspectedon-sitebyourAgency,butrequiringon-siteinspectionduetochanges/additionsintroduced,or

4.Manufacturingsitespreviouslyinspectedon-sitebyourAgency,butnotmeeting thecriteriaofArticleBoftheGuideline.

Foron-siteinspectionapplicationstobesubmittedbyimportingcompaniesunder Articles1,3,and4,inspectionplanningiscarriedoutaccordingtotheorderofpriority designationaccordingtotheGuidelineontheOperatingPrinciplesandProceduresofPriority AssessmentBoardforHumanMedicinalProducts.ProductsauthorizedbyourAgencybefore 2010,applicationstobemadeunderArticle2,andapplicationsforproductsthathaveused theirrighttotwoorthreerisk-basedinspectionsinlinewiththeGuidelinebutfailtomeetthe conditionsofArticleBoftheGuideline,areincludedintheinspectionplanningwithoutbeing subjecttoprioritization.

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 16of34 Anon-siteinspectionapplicationmustbeattachedwithAnnex1,Annex2andAnnex 3,thetableinAnnex9properlycompleted,andthedocumentslistedinAnnex4,complete andwithoutanyomissions. B.CircumstancesandPrinciplesforPaper-BasedInspections Anapplicationforpaper-basedinspectionmaybesubmitted:

a)forGMPcertificationofdifferentstrengthsofaproductpreviouslyinspectedon- sitebyourAgency,

b)forGMPcertificationofproductswithadifferentformulation/pharmaceuticalform (injector,pen,etc.),manufactured/tobemanufacturedusingthesamelineandthesame

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

equipmentasthoseofaproductpreviouslyinspectedon-sitebyourAgency,
c)forGMPcertificationofanotherproducttobemanufacturedbyanothercompany
establishedinTürkiyeusingthesamelineandthesameequipmentatamanufacturingsite
previouslyinspectedon-sitebyourAgency,
ç)forGMPcertificationuponrequestbythesameoranothercompanyofanother
productmanufactured/tobemanufacturedusingadifferentlineandequipmentinthesame
buildingastheonehousingthelineandequipmentusedformanufacturingproducts
previouslyinspectedon-sitebyourAgency,
d)forproductspresentedwithasolventwhichisproducedatadifferent
manufacturingsitethantheonewheremanufacturingstepsoftheproductwarrantingon-site
inspectionareperformedunderthisguideline,wherethemanufacturingsiteoperatesina
countryhometoacompetentauthoritypartytoPIC/s,regardlessofwhetherornotpreviously
inspectedbyourAgency,or
e)whereaGMPcertificateisrequested,bythesameoradifferentcompany,forthe
additionofadifferentactivitynotpreviouslyinspectedbyourAgencybutlocatedinthesame
buildingandusingthesameproductionlinesandequipmentastheproductsthathavebeen
previouslyinspectedon-sitebyourAgency(e.g.,arequestfortheinspectionofprimary
packagingactivitiesatafacilitywherebulkproductionactivitieshavebeeninspectedbyour Agency).
f)whereaGMPcertificateisrequested,bythesameoradifferentcompany,for
productsmanufacturedortobemanufacturedinabuildingdifferentfromtheonewhere
productspreviouslyinspectedon-sitebyourAgencyareproduced,providedthatthe
manufacturingsiteoperatesinacountrywithaPIC/smemberauthorityandtheproduction
activitiesrelatetoallproductgroupsexceptfortheactivesubstanceproductionofbiological
andbiotechnologicalproducts.
g)forGMPcertificationofaco-marketedproducthavingthesameoradifferent
strength,manufacturedatthesamemanufacturingsite,usingthesameequipmentandthe
sameformulationasthoseusedforaproductpreviouslygrantedGMPcertification.
Dependingonwhetherthemanufacturingsitehadbeenpreviouslyinspectedbyour
Agency,theapplicationmustbesubmittedunderthedocumenttype:“ForeignGood
ManufacturingPractices(GMP)Paper-basedInspectionAssessmentApplicationperProduct
forMarketingAuthorization(excludingcertification)(ifaninspectionhaspreviouslybeen
carriedoutatthefacilityonbehalfoftherelevantcompany)(co-marketingproductsshall
alsobeevaluatedwithinthisscope)”or“ForeignGoodManufacturingPractices(GMP)
Paper-basedInspectionAssessmentApplicationperProductforMarketingAuthorization
(excludingcertification)(ifanon-siteinspectionhasnotpreviouslybeencarriedoutatthe
facilityonbehalfoftherelevantcompany).”

Inpaper-basedinspectionapplications,itismandatorythatthereferenceproducts
havebeeninspectedon-siteandfoundcompliant.Forthispurpose,indeterminingthevalidity
periodofthecertificatetobeissued,therelevantinspectionconductedbyourAgencyshallbe
takenasthebasisforpoints(a),(b),(c),(ç),(e),(f),and(g),whileforpoint(d),themost
recentinspectionofthefacilitycarriedoutbyaPIC/smemberauthorityshallbetakenasthe
basis.Furthermore,inpaper-basedinspectionapplicationstobemadebasedonproductsthat
havebeeninspectedwithinthescopeofon-siteinspectionunderthisGuidelineandforwhich
thevalidityperiodoftheGMPcertificatehasbeenextendedbyourAgencyasaresultofrisk-
basedinspection,thevalidityperiodofthecertificateshallapply.Anapplicationwillnotbe
admissibleforproductswhichhadbeendeniedcertificationfollowinganon-siteinspection.
ForapplicationstoourAgencyunderArticleB:
Wherepoint(a)isapplicable,theformsspecifiedinAnnex1,Annex2andAnnex3
andtheletterofcommitmentinAnnex5mustbesubmitted;

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Wherepoint(b)isapplicable,theformsspecifiedinAnnex1,Annex2andAnnex3, theletterofcommitmentinAnnex5,andthedocumentslistedinAnnex6(excludingAnnex 6.9)mustbesubmitted; Wherepoint(c)isapplicable,theformsspecifiedinAnnex1,Annex2andAnnex3, theletterofcommitmentinAnnex5(maybesubmittedtoourAgencydirectlybythe inspectee),andthedocumentslistedinAnnex6(excludingAnnex6.9)mustbesubmitted(c); Wherepoint(ç)isapplicable,theformsspecifiedinAnnex1,Annex2andAnnex3, theletterofcommitmentinAnnex5(maybesubmittedtoourAgencydirectlybythe inspectee),andthedocumentslistedinAnnex6mustbesubmitted; Wherepoint(d)isapplicable,theformsspecifiedinAnnexes1,2,and3,thetablein Annex9,andthedocumentsinAnnex8shallbesubmitted. Points(e)and(f)mayonlybeapplicableincaseswheretheconditionsofpoint(ç) cannotbemet.Wherepoints(e)and(f)areapplicable,theformsspecifiedinAnnex1, Annex2andAnnex3,theletterofcommitmentinAnnex5,andthedocumentsinAnnexes9 and6shallbesubmitted. Wherepoint(g)isapplicable,theformsspecifiedinAnnex1,Annex2andAnnex3, theletterofcommitmentinAnnex5,acopyofthemarketingauthorizationfortheproduct designatedforco-marketing,adocumentshowingthatco-marketingauthorizationhasbeen grantedtoanaturalpersonorcommercialcompanyotherthantheauthorizedrepresentativein Türkiye,theco-marketingagreementincludingthewrittenapprovalsofthenaturalpersonsor commercialcompaniesinvolvedinco-marketing,andthecommercialregistrycertificatesof thepartiesshallbesubmitted,selectingthedocumenttype“ForeignManufacturingSites GoodManufacturingPractice(GMP)Paper-BasedInspectionAssessmentApplicationfor EachProductProvidingBasisforMarketingAuthorization(excludingcertification)(ifan inspectionhadbeenconductedatthemanufacturingsiteforthisapplicant)(co-marketed productswillbealsoconsideredin-scope.”Ifthemanufacturerisacontractcompany,the agreementmadewiththeoriginatorcompanymustalsobesubmitted.

Furthermore,forapplicationsunderArticleB,theimportermustexpresslyspecifyin thecoverlettersthepointunderwhichtheapplicationhasbeensubmitted.

C.CircumstancesandPrinciplesforRisk-BasedInspections

Anapplicationforrisk-basedinspectionmaybesubmitted: RequestsfortheextensionofthevalidityperiodofGMPcertificatesmayonlybe madeforproductsthathavebeenfoundcompliantasaresultofon-siteinspectionsand/or paper-basedinspectionsconductedbyourAgencyandforwhichaGMPcertificatehasbeen issued. Risk-basedinspectionapplicationsmustbesubmittedwithinamaximumofsix monthspriortotheexpirydateofthecertificate,takingintoaccountthenecessaryapplication, evaluation,andcertificationprocesses. TheformsinAnnex1,Annex2andAnnex3,filledoutcompletely,andthe documentsinAnnex7,withoutanyomissions,mustbesubmittedwithanapplicationforrisk-basedinspection.

12.Annexes Annex1.ApplicationFormfortheProduct 1-Productname: 2-Pharmaceuticalform: 3-Activesubstance: 4-Dose: 5-MarketingauthorizationstatusinTürkiye: Authorized(marketingauthorizationdateandnumber) Pendingmarketingauthorization(applicationdateandnumber) Nomarketingauthorizationapplication 6-Product: Referenceproduct Equivalentproduct Biosimilar 7-Ifanequivalent/biosimilarproduct,arethereanysubstitutes? Yes No 8-Producttype: Conventional Biotechnological Biosimilar Biologic AdvancedTherapyMedicinalProduct TraditionalHerbalMedicinalProduct AllergenicProduct Other(brieflydescribe) 9-Forsterileproduct,manufacturingmethod: TerminalSterilization AsepticManufacturing Iattesttothetruthfulnessoftheinformationprovidedabove. Applicant’sauthorizedrepresentative:

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

Name: Position: Signature Date:.../.../...

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 20of34 TableTemplate: ProductName:..... Manufacturing SiteName- Address- DUNS Manufacturing SiteName- Address- DUNS Manufacturing SiteName- Address- DUNS Semi-finishedproduct(operations performed)manufacturing* Bulkmanufacturing Primarypackaging Terminalsterilization(ifapplicable) Secondarypackaging QualityControlTestsforFinished ProductBatchRelease FinishedProductBatchRelease SolventProduction(incaseswhere thereareactivitiesrelatedtosolvent productionatotherfacilities,this mustbenotifiedtousunderthe "Other"heading) Other: *Ifthesemi-finishedproductmanufacturingactivityiscarriedoutatadifferentfacilityorat multiplefacilities,themanufacturingstepsperformedmustbespecifiedindetailwithin parentheses. Iattesttothetruthfulnessoftheinformationprovidedabove. Applicant'sauthorizedrepresentative: Name: Position: Signature Date:.../.../...

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 21of34 Annex2.ApplicationFormfortheActiveSubstance Forbiotechnological/biosimilarproductsandbiologicswithabiologicallyderived activesubstance,therelevantarticlesofthetablebelowmustbecompleted,inadditiontothe tableabove. TableTemplate: ActiveSubstanceName:..... Manufacturing SiteName- Address- DUNS Manufacturing SiteName- Address- DUNS Manufacturing SiteName- Address- DUNS ActiveSubstanceManufacturing* *Iftheactivesubstancemanufacturingactivityiscarriedoutatadifferentfacilityorat multiplefacilities,theproductionstepsperformedmustbespecifiedindetailwithin parentheses. Iattesttothetruthfulnessoftheinformationprovidedabove. Applicant'sauthorizedrepresentative: Name: Position: Signature Date:.../.../...

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 22of34 Annex3.ApplicationFormfortheManufacturingSite ManufacturingSiteName: (AsStatedontheManufacturingAuthorizationIssuedbytheCompetentAuthority Concerned). ManufacturingSiteAddress: (AsStatedontheManufacturingAuthorizationIssuedbytheCompetentAuthority Concerned). Telephone: Fax: E-mail: NameofPersoninCharge: ManufacturingAuthorizationDate/Number: GMPCertificateDate/Number: Iattesttothetruthfulnessoftheinformationprovidedabove. Applicant'sauthorizedrepresentative: Name: Position: Signature Date:.../.../...

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Annex4.A.1CurrentSiteMasterFilewithannexes(smf.pdf)
Annex4.A.2GMPCertificateandManufacturingAuthorizationofthemanufacturing site,bothcurrent(sertifika.pdf)
Annex4.A.3Thelastinspectionreportforthemanufacturingsite,coveringthe manufacturingarea/lineusedfortheproduct(s),andadescriptionofanycorrectiveand preventiveactionstakenatthemanufacturingsite,ifapplicable(rapor.pdf)(excluding inspectionreportsissuedbyourAgency)
Annex4.A.4Whetheranyoftheproductsmanufacturedwererecalledoverthepast5 years,andifso,astatementandbriefexplanationbythemanufacturerregardingthecountries whereth erecallsoccurred,andanyproductdefectsreportedtolocalorinternational pharmaceuticalauthorities.(hata.pdf)
Annex4.A.5Astatement/declarationexplainingthereasonsfortheapplicant's inabilitytomeetthecriteriaofArticleBoftheGuidelineonApplicationsforGMPInspection

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

ofForeignManufacturingSites,andthegroundsforapplication.
Annex4.A.6.DecisionLetteroftheProrityEvaluationBoardforOn-SiteInspection ApplicationstoBeSubmittedunderArticles1,3,and4 Annex4.BTechnicalParticularsoftheProduct Annex4.B.1Alistshowingstorageconditionsoftheproducts(temperature,humidity) (stabilityreportsnotrequired)(saklama.pdf)
Annex4.B.2Manufacturingflowdiagram(ifmultiplesitesareinvolved,thenameof thesiteinvolvedshouldbeindicatednexttoeachstep)andanoverviewofallmanufacturing steps(uretim.pdf) Annex4.B.3Finishedproductreleasespecifications(spesifikasyon.pdf) Annex4.B.4Abriefdescriptionoftheconditionsthatwillbeobservedduring transport:themeansoftransportationtobeused,theequipmenttobedeployed(e.g., Styrofoam,dataloggerforcold-chainproducts),andhowthesewillbeprocured. (sevkiyat.pdf)

Annex5.LetterofCommitment
Acommitmentlettermustbesubmitted,preparedbythemanufacturer'squality assuranceofficer,productionmanager,orresponsiblemanager,indicatingallproduction stages(weighing,bulkproduction,primaryandsecondarypackaging,etc.)andspecifyingthe roomandequipmentnumbersofeachsection(toallowcomparisonwiththeroomsand equipmentusedintheproductionofproductspreviouslyinspectedon-site)andconfirming thattheproductinquestionismanufacturedinaccordancewiththerequirementsofArticleB oftheapplication,usingthesameordifferentproductionlines,thesameordifferent equipment,andthesameorsimilarprocessflow,andincludingthenameofthereference productthatwasinspectedon-siteandthedateofitsinspection(taahhut.pdf).
Tabletemplateforattachingtotheletterofcommitment: ComparativeTableofRoomsandEquipment Manufacturi ngStep Building Room Equipment Nameofon- siteinspected product Nameof product proposedfor paper-based inspection Nameofon- siteinspected product Nameof product proposedfor paper-based inspection Nameofon- siteinspected product Nameof product proposedfor paper-based inspection 1Weighing BuildingA BuildingA A.024 A.024 Scale#1 Scale#1 2Formulation BuildingB BuildingB B.044 B.044 Mixingtank (IDMX###) Mixingtank (IDMX###) 3Filling BuildingB BuildingB B.046 B.046 Filing equipment (FE###) Filling equipment (FE###) 4... ... ... Authorizedapprover'sname: Position: Signature Date:.../.../

Annex6.RequisiteDocumentsforPaper-BasedInspectionApplications
Annex6.A.TechnicalParticularsoftheManufacturingSite
Annex6.A.1CurrentSiteMasterFilewithannexes(smf.pdf)
Annex6.A.2GMPCertificateandManufacturingAuthorizationofthemanufacturing site,bothcurrent(tesissertifika.pdf)
Annex6.A.3Thelastinspectionreportforthemanufacturingsite,coveringthe manufacturingarea/lineusedfortheproduct(s),andadescriptionofanycorrectiveand preventiveactionstakenatthemanufacturingsite,ifapplicable(rapor1.pdf)(excluding inspectionreportsissuedbyourAgency)
Annex6.A.4Regardlessofwhetherthemanufacturingsiteislocatedinacountry partytoPIC/s,thereportfromthelastinspectionconductedbyanotherauthoritypartyto PIC/soverthepast3years,coveringthemanufacturingline/areaoftheproduct(s)(rapor2.pdf) (excludinginspectionreportsissuedbyourAgency)
Annex6.A.5Alistofallinspectionsconductedatthemanufacturingsiteoverthepast 10years,includingthoseconductedbyourAgency,withalistshowingwhetherobservations fromsaidinspectionhavebeenresolved(denetimliste.pdf)
Annex6.A.6Whetheranyoftheproductsmanufacturedatthissitewererecalledsince inspectionbyourAgency,andifso,astatementandbriefexplanationbythemanufacturer regardingthecountrieswheretherecallsoccurred,andanyproductdefectsreportedtolocal

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

orinternationalpharmaceuticalauthorities(hata.pdf). Annex6.BTechnicalParticularsoftheProduct
Annex6.B.1Alistshowingstorageconditionsoftheproduct(s)(temperature, humidity)(saklama.pdf)
Annex6.B.2Anoverviewoftheproductformulation,manufacturingflowdiagram
andallmanufacturingsteps(uretim.pdf)
Annex6.B.3Activesubstanceandfinishedproductspecifications(spesifikasyon.pdf)
Annex6.B.4Adescriptionoftheconditionsthatwillbeobservedduringtransport (sevkiyat.pdf)
Annex6.B.5Cleaningvalidationreport*(temizlik.pdf)
Annex6.B.6Processvalidationreport**(proses.pdf) Annex6.B.7Stabilityreport**(stabilite.pdf)
Annex6.B.8Anypertinentdocuments,iftheactivesubstanceorexcipientsrequire
specialconditions(humidity,light,etc.),differenttothoserequiredfortheproductpreviously
inspectedandcertifiedGMPcompliant(ozel.pdf).

Annex6.B.9Operationalandperformancequalification(OQandPQ)reportsforthe
linesandequipmentwhichareusedformanufacturingtheproductssubjecttoinspectionbut
whichhadnotbeenincludedinthepreviousinspection(kalifikasyon.pdf)
Annex6.B.10Alistofanyotherproductsmanufacturedusingthesamebuilding,
room,orequipmentastheproducttobeinspectedmustbesubmitted,includingtheactive
substancescontainedbytheseproductsandtheirpharmacologicalclasses(e.g.hormone,
cytotoxic)(ekipmanortak.pdf),
Annex6.B.11Alistofactivesubstances,excipientsandprimarypackagingmaterials
usedinthemanufactureoftheproducttobeinspected,andsupplierstthereof,alongwiththe
mostrecentactualauditsofsuchsuppliers(tedarikci.pdf).
*Wherecleaningvalidationstudieshavenotbeencompletedandanapplicationformarketing
authorizationoravariationtothemarketingauthorizationtermshasbeenmadetoourAgencybefore
thebatcheshavebeenplacedontheTurkishmarket,withapossibilityofcompletingandsubmitting
saidstudies,itmaybeacceptabletosubmitthecleaningvalidationprotocol.Thissituationshouldbe
statedbytheapplicantandsupportedbyaletterofcommitment.If,inareviewconductedbythe
manufacturer,theproductcoveredbytheinspectionhadnotbeenusedasworst-caseinthecleaning
validationmatrixassessmentcoveringallmanufacturingequipment,cleaningvalidationreports
involvingotherproductswhichhadbeenusedasworst-caseshouldbesubmittedtoourAgency.
**Whereprocessvalidationandstabilitystudieshavenotbeencompletedandanapplicationfor
marketingauthorizationoravariationtothemarketingauthorizationtermshasbeenmadetoour
AgencybeforethebatcheshavebeenplacedontheTurkishmarket,withapossibilityofcompleting
andsubmittingsaidstudies,itmaybeacceptabletosubmittheprocessvalidationprotocolandthe
stabilityvalidationprotocol.Thissituationshouldbestatedbytheapplicantandsupportedbyaletter
ofcommitment.

Annex7.RequisiteDocumentsforRisk-BasedInspectionApplications
Annex7.A.TechnicalParticularsoftheManufacturingSite
Annex7.A.1CurrentSiteMasterFilewithannexes(smf.pdf)
Annex7.A.2GMPCertificateandManufacturingAuthorizationofthemanufacturing
site,bothcurrent(tesissertifika.pdf)
Annex7.A.3Ifthemanufacturingsiteislocatedinacountrypartyto PIC/s,thelast
inspectionreportissuedbythelocalcompetentauthorityforthemanufacturingsite,covering
themanufacturingarea/lineusedfortheproduct(s)(rapor1.pdf)
Annex7.A.4Regardlessofwhetherthemanufacturingsiteislocatedinacountry
partytoPIC/s,thereportfromthelastinspectionconductedbyanothercompetentauthority
partytoPIC/soverthepast3years,coveringthemanufacturingline/areaoftheproduct(s)
concerned(rapor2.pdf)(excludinginspectionreportsissuedbyourAgency)

sion published by the Turkish Medicines and Medical Devices Agency (TİTCK), imported from the AIFD Legislation Portal archive. In the event of any discrepancy, the Turkish original text (mevzuat.g

Annex7.A.5Alistofallinspectionsconductedatthemanufacturingsiteoverthepast 10years,includingthoseconductedbyourAgency,withalistshowingwhethertheproduct(s) subjecttotheapplicationcoverthemanufacturingline/site(denetimliste.pdf)
Annex7.A.6Alistofallchangesinthefacilities,equipmentandauxiliarysystems usedfortheproductscoveredbytherisk-basedinspectionapplicationsincetheon-site inspectiondate(degisikliktesis.pdf),
Annex7.A.7Whetheranyoftheproductsmanufacturedatthissitewererecalledsince inspectionbyourAgency,andifso,astatementandbriefexplanationbythemanufacturer regardingthecountrieswheretherecallsoccurred,andanyproductdefectsreportedtolocal orinternationalpharmaceuticalauthorities(hata.pdf).

Annex7.BTechnicalParticularsoftheProduct
Annex7.B.1Manufacturingflowdiagramandanoverviewofallmanufacturingsteps (uretim.pdf)
Annex7.B.2Alistofanyotherproductsmanufacturedusingthesamebuilding,room, orequipmentastheproducttobeinspected,includingtheactivesubstancescontainedby theseproductsandtheirpharmacologicalclasses(e.g.hormone,cytotoxic)(ekipmanortak.pdf)
Annex7.B.3GMPcertificateissuedbyourAgency(themostrecentversionifany notationsweresubsequentlyadded)(urunsertifika.pdf)
Annex7.B.4Alistofanychangesrelatedtotheproductcoveredbytherisk-based inspectionapplicationsincetheon-siteinspectiondate(degisiklik.pdf)
Annex7.B.5Alistsummarizinganycorrectiveactionstakentoaddresscritical deviationsorcomplaintsreceivedsincetheon-siteinspectiondate,regardingtheproduct coveredbytherisk-basedinspectionapplication(sapma.pdf)
Annex7.B.6Alistofactivesubstances,excipientsandprimarypackagingmaterials usedinthemanufactureoftheproducttobeinspected,andsupplierstthereof,alongwiththe mostrecentactualauditsofsuchsuppliers(tedarikci.pdf)”
Annex7.B.7Appendix10tables,coveringthemanufacturingsteps,buildings,rooms andequipmentseen/assessedduringthelaston-siteinspectionfortheproductscoveredinthis application(allarticlesusedforweighing,bulkproduction,primaryandsecondarypackaging, etc.(karsilastirma.pdf) Annex7.B.8Ifcold-chainshippingisrequired,alistofanydeviationsduring shipmentstoTürkiyeandtheactionstaken(sogukzincir.pdf).

Annex8RequisiteDocumentsUnderArticleB,Pointd
Annex8.1CurrentSiteMasterFilewithannexes(smf.pdf).
Annex8.2GMPCertificateandManufacturingAuthorizationofthemanufacturing site,bothcurrent(tesissertifika.pdf)
Annex8.3Thelastinspectionreportissuedoverthepast3yearsbyacompetent authoritypartytoPIC/s,alsocoveringsolventproductionoperations(rapor1.pdf)
Annex8.4Regardlessofthescopeofinspection,thelastinspectionreportissuedover thepast3yearsbyanon-localcompetentauthoritypartytoPIC/s(rapor2.pdf)(excluding inspectionreportsissuedbyourAgency)
Annex8.5Whetherarecallcoveringallproductsmanufacturedatthissiteoccurred overthepast5years,andifso,astatementandbriefexplanationbythemanufacturer regardingthecountrieswheretherecallsoccurred,andanyproductdefectsreportedtolocal orinternationalpharmaceuticalauthorities(hata.pdf).
Annex8.6Alistshowingthestorageconditions(i.e.temperatureandhumidity)for thesolvent(stabilityreportsnotrequired)(saklama.pdf)
Annex8.7Amanufacturingflowdiagramandoverviewofallmanufacturingsteps (uretim.pdf)
Annex8.8Releasespecificationsforthesolvent(spesifikasyon.pdf)
Annex8.9Abriefdescriptionoftheconditionsthatwillbeobservedduringtransport: themeansoftransportationtobeused,theequipmenttobedeployed(e.g.,Styrofoam,data

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loggerforcold-chainproducts),andhowthesewillbeprocured.(sevkiyat.pdf)

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 30of34 Annex9.TableofManufacturingSteps,Buildings,RoomsandEquipment Aseparatetablesignedbythemanufacturer'squalityassuranceofficer,manufacturing officerorqualifiedpersonwillbeprovidedforeachproduct/activesubstanceandsolvent, beginningwiththeweighingstep. Tabletemplate: Productname:...mg...vial Manufacturingstep Building Room Equipment 1 Weighing BuildingA A.024 Scale#1 2 Formulation BuildingB B.044 Mixingtank(IDMX###) 3 Filling BuildingB B.046 Fillingequipment(IDFE###) 4 ... ... AuthorizedApprover Name: Role: Signature Date:.../.../

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 31of34 Annex10.ComparativeTableofManufacturingSteps,Buildings,Roomsand Equipment Aseparatetablesignedbythemanufacturer'squalityassuranceofficer,manufacturing officerorqualifiedpersonwillbeprovidedforeachproduct/activesubstanceandsolvent, beginningwiththeweighingstep. Tabletemplate: Productname: Manufactu ringstep Building Room Equipment Manufact ured duringthe on-site inspection on.../.../ .... Manufactu redduring orafterthe application period under ArticleC Manufactu redduring theon-site inspection on.../.../ .... Manufacture dduringor after the application periodunder ArticleC Manufactur edduring theon-site inspection on.../.../... . Manufactur edduringor afterthe application period under ArticleC 1 Weighing Building A BuildingAA.024 A.024 Scale#1 Scale#1 2 FormulationBuilding B BuildingBB.044 B.044 Mixing tank(ID MX##1) Mixingtank (ID MX ##2) 3 Filling Building B BuildingBB.046 B.046 Filling equipment (ID FE ###) Filling equipment (IDFE###) 4 ... ... AuthorizedApprover Name: Role: Signature Date:.../.../

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 32of34 Annex11.TableofVariationsReportablebyImporters Variation TypeofReview RiskAssessmentAction Formalerrors/minor correctionsinGMPcertificate Administrative LowRisk StampedonGMP certificate Changeofimporter Administrative LowRisk StampedonGMP certificate Manufacturingsitename change Administrative LowRisk StampedonGMP certificate Manufacturingsiteaddress change Administrative LowRisk StampedonGMP certificate Productnamechange Administrative LowRisk StampedonGMP certificate Variationsinvolving room/line/equipment changes/additionswithinthe samebuildingatthe manufacturingsite Technical Moderaterisk Approval/rejection communicatedto applicantbasedon reviewbythe Inspectorsofour Agency. Additionofnewbuildings/ newactivitiesatthe manufacturingsite Technical HighRisk Aninspection applicationshallbe submittedwithinthe scopeofthe Guideline.

DocumentNumber InitialIssueDate RevisionDate RevisionNumber Page İDD-KLVZ-21 06.03.2015 22.09.2025 10 33of34 13.Effectiveness ThisGuidelinebecomeseffectiveonthedateitispublished. RevisionHistory RevisionDescription EffectiveDate R.00 Initialissue. 06.03.2015 R.01 Updatedtoalignwithfullmembershipin PIC/s. 15.02.2018 R.02 Updatedtoincorporaterisk-basedapproachtoalign withourAgency'sPIC/smembershipandGMP InspectionRelianceGuidelineandcurrentneeds. 02.07.2018 R.03 UpdatedtoalignwithourAgency'squalitysystem. AddedarticlesPurpose,Scope,LegalBasis, DefinitionsandAbbreviations,andelaboratedthe process.Addedchecklistsandtablesusedforthe processes. 20.09.2022 R.04 AssignedaGuidelineDocumentNumbertoalign withourAgency'sQualitySystemDocumentation system. 15.11.2022 R.05 UpdatedtoreflectourAgency'seffortstobe recognizedinthelistofregulatoryauthorities maintainedbyWorldHealthOrganization(WHO) 27.12.2022 R.06 RevisedArticle7.5oninspectionrequirementsfor allergenicproducts,Article7.13onconductof inspections,andAnnex12ondivided manufacturingsteps. 07.07.2023 R.07 AddedArticle10.ProvisionsforGMPInspections

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UndertheExpeditedMarketingAuthorization ProcedureBasedonCollaborationwithWHO 18.09.2023
R.08 AddedArticles8.7,8.8andAnnex4.A.5on inspectionrequirements.Expandedontheon-site inspectionnormsandremovedthewording “Productgroupsotherthanbiologicand biotechnologicalactivesubstances”frompointçon paper-basedinspections. 05.10.2023 R.09 Revisionshavebeenmadeinsemi-finishedproduct andhomeopathicstockproductionfacilities,and newpointshavebeenaddedtothearticleon “CircumstancesandGeneralPrinciplesfor ConductingPaper-BasedGMPInspectionsat ForeignManufacturingSites” 07.06.2024

R.10 -Provisionshavebeenaddedregardingthe possibilityofsubmittinguptothreerisk-based inspectionapplicationsifthefacilitysubjecttothe applicationislocatedinaPIC/smembercountry. -Aprovisionhasbeenaddedconcerningthe inclusionofproductsholdingGMPcertificates, issuedfollowinganapplicationunderArticlesBand CoftheGuideline,inthescopeofthefirston-site inspectiontobeconductedatthefacility(8.6). -TheGMPcertificateextensionperiodhasbeen updatedto12months(8.10,former8.9). -Revisionshavebeenmaderegardingthe subsequentadditionofactivitiesnotsubjectto mandatoryinspectiontothecertificate.(8.11) -ThetableinAppendix11hasbeenupdatedinline withthechangesmade. 22.09.2025

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